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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,260	02/13/2002	Domenica Simms	0942.5170001/RWE/ALS	6799

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WASHINGTON, DC 20005

EXAMINER
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BAUSCH, SARAE L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/073,260	<b>Applicant(s)</b> SIMMS ET AL.	
	<b>Examiner</b> Sarae Bausch	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11,16-18,21-25,27-31,55-57,61-63 and 66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11,16-18,21-25,27-31,55-57,61-63 and 66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. This action is written in response to applicant's correspondence submitted on 06/19/2006.
2. Currently, claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66 are pending in the instant application. Claim 12-15, 19-20, 26, 32-54, 58-60 and 64-65 have been canceled. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented or are reiterated from the previous office action. Response to arguments follow. This action is **FINAL**.

### ***Withdrawn Rejections***

3. The rejections of claims 57 and 62, under 35 U.S.C. 112, second paragraph, made in section 12 page 4 of the previous office action mailed 12/19/2006, is withdrawn in view of the amendment to the claims.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112- New Matter***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63 and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amendment to claims 1, 31, and 55 to recite “a first filter directly on top of a second filter” is not supported by the specification and raises the issue of new matter. The specification disclose a filtration apparatus assembled by placing a second filter into a cartridge housing placing a first filter on top of the second filter and securing the first and second filter with an insert (see paragraph 46). However, the specification does not teach a first filter directly on top of a second filter nor does the specification define the term “directly”. The specification does, not disclose if directly refers to a first filter in a straight line/direction with a second filter, a first filter immediately followed by a second filter, a first filter and a second filter with nothing in between the filters, or a first filter contacting a second filter. The specification discloses a figure of the filtration apparatus, figure 8a-8b, however figure 8a depicts a first filter on top of a second filter but does not depict if the first filter is directly on top of a second filter in such a manner that would clearly disclose that the first filter is immediately followed by a second filter, the first filter is contacting the second filter or if the first and second filters have nothing in between the filters. As the specification does not define the term “directly”, the addition of the term “directly” changes the scope of the claims and the specification does not provide support for a first filter directly on top of a second filter.

***Maintained Rejection***

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66, are rejected under 35 U.S.C. 102(b) as being anticipated by Jones (PCT WO95/02049). Jones teaches a method of separating biological compounds from cells by filtration using two filters with increasing pore size in the direction of sample flow. This rejection was previously presented in section 12 of the office action mailed 12/19/2005 and is reiterated below.

With regard to claim 1, Jones (WO95/02049) teaches a method of purifying DNA (biological macromolecule) from *E. coli* bacterial culture (biological sample) by passing the cells through a 1  $\mu$ m filter followed by a 20 $\mu$ m filter (page 22, 1<sup>st</sup> full paragraph). Jones et al. teaches that the method can be used for genomic DNA (see page 4, 1st paragraph).

With regard to claim 2, Jones teaches the method of purifying nucleic acid from cells that comprises lysing a cell suspension to form a cell lysate containing nucleic acid and applying the cell lysate to a filter to remove unwanted cells and cell debris (page 2, 4<sup>th</sup> full paragraph).

With regard to claims 3-5, Jones teaches that any cell producing a target compound may be used in their invention. Jones defines a “cell” to encompass bacterial cells, cells from higher organisms for example blood cells, phage particles, and other cell types or organelles which

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contain the target compound and may require some form of lysis step to release it (page 3, 4<sup>th</sup> full paragraph). The cells are lysed prior to applying to the first filter (page 2, 4<sup>th</sup> full paragraph).

With regard to claims 6-11, Jones teaches that the target compound to be separated may comprise nucleic acid (instant claim 6), protein, or other desired compounds, in particular purifying recombinant proteins and antibodies (instant claim 7)(page 2, 2<sup>nd</sup> and 3<sup>rd</sup> paragraph). Jones further teaches that RNA or DNA may be purified using this invention (page 5, 2<sup>nd</sup> paragraph) (instant claim 8-11).

With regard to claims 16-18, Jones teaches the use of two filter layers to purify DNA from bacterial cells, with the first filter having 1 $\mu$ m pore size and the second filter having 20  $\mu$ m pore size (instant claims 16-18) (page 22, 1<sup>st</sup> full paragraph).

With regard to claims 21-25 and 27, Jones teaches the use of a first filter that retains unwanted cells and cell debris (instant claim 21), that is made of any material that can tolerate the reagents such as cellulose acetate (acetylated cellulose) (instant claim 24 and 25) and is no greater than 50  $\mu$ m in pore size and no smaller than .2  $\mu$ m (instant claim 22-23) (page 6, 1<sup>st</sup> full paragraph). Jones teaches that for a nucleic acid, the filter is typically glass or resin based and can bind the nucleic acid such as borosilicate glass (see page 6, 2<sup>nd</sup> paragraph) (claim 24). Jones teaches that the first filter is no greater than 50  $\mu$ m in pore size and no smaller than .2  $\mu$ m (see page 6, 1<sup>st</sup> paragraph) and the second filter is a 20  $\mu$ m pore size (see page 22, 1<sup>st</sup> full paragraph) (instant claim 27).

With regard to claim 28 and 29, Jones teaches the method of a membrane filter that is placed inside the column (tube) (instant claim 29) and has a cylindrical shape (instant claim 28) (page 11, last paragraph, figure 1 and figure 2).

With regard to claims 30-31, Jones teaches the method of lysing a cell suspension to form a cell lysate, applying the cell lysate to a filter to remove unwanted cells and cell debris, contacting the filtered lysate with a solid phase matrix, separating the resultant filtered lysate from the matrix, and eluting the nucleic acid from the matrix (page 2, 4<sup>th</sup> full paragraph). Jones teaches the method of purifying plasmid DNA by using a filtration method of increasing pore sizes of two filters using a 1  $\mu\text{m}$  filter followed by a 20  $\mu\text{m}$  filter and promoting the flow of lysate through the filters by positive pressure (page 22, 1<sup>st</sup> full paragraph).

With regard to claim 55-57 and 61-63, Jones teaches the method of lysing a cell suspension from *E. coli* (natural source) to form a cell lysate, applying the cell lysate to a filter to remove unwanted cells and cell debris, followed by contacting the filtered lysate with a solid phase matrix, separating the resultant filtered lysate from the matrix, and eluting the nucleic acid from the matrix (page 2, 4<sup>th</sup> full paragraph). Jones teaches the method of purifying plasmid DNA (instant claim 57) by the method of increasing the pore sizes of the filters (instant claim 55), by using a 1  $\mu\text{m}$  cellulose acetate filter followed by a 20  $\mu\text{m}$  PTFE filter (instant claim 61-62) and promoting the flow of lysate through the filters by positive pressure (instant claim 56) (page 22, 1<sup>st</sup> full paragraph and Table 1, page 21). Jones teaches that for a nucleic acid, the filter is typically glass or resin based and can bind the nucleic acid such as borosilicate glass (see page 6, 2<sup>nd</sup> paragraph) (claim 63).

With regard to claim 66, Jones et al. teaches two filters that have the inherently property of shearing genomic DNA, as evidenced by applicant's own specification (see page 13, last paragraph to page 14, 1<sup>st</sup> line).

***Response to Arguments***

8. The response traverses the rejection on page 11 of the response mailed 06/19/2006. The response asserts that the present invention discloses a filtration apparatus comprising 2 filters with a first filter directly on top of a second filter so that the first filter is contacted with a sample before the second filter and Jones discloses two filters separated by a conduit and a chamber, thus the present claims are novel over Jones. This response has been thoroughly reviewed but not found persuasive. Claim 1 recites a method “comprising” a filtration apparatus with a first filter directly on top of a second filter in which the first filter is contacted with the biological macromolecules before the second filter, however the claim does not require nor recite that the first filter is contacted by a second filter nor does the specification provide a definition for the term “directly”. Jones et al. does teach a first filter that is in a direct line to a second filter and therefore the first filter is directly on top of the second filter (see figure 5). The instant pending claims does not exclude additional elements, such as two filters separated by a conduit and chamber as taught by Jones et al. and the amendment to recite “a first filter directly on top of a second filter” requires only that the first filter be in a straight line or direction to the second filter. Therefore, Jones anticipates the claimed invention. For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

***Conclusion***

9. No claims are allowable.



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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Schukla can be reached on (571)272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

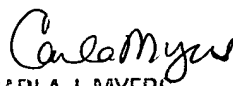
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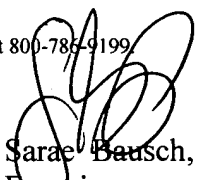
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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CARLA J. MYERS  
PRIMARY EXAMINER

  
Sarae Bausch, PhD  
Examiner  
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